UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/622,220 | 07/18/2003 | Matthew L. Nilles | 3128-6046US | 5964 |

24247 7590 04/16/2007
TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

| EXAMINER | |
|---|---|
| NAVARRO, ALBERT MARK | |
| ART UNIT | PAPER NUMBER |
| 1645 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 04/16/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/622,220 | NILLES ET AL. | |
| | Examiner | Art Unit | |
| | Mark Navarro | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5 and 7-49* is/are pending in the application.

4a) Of the above claim(s) *7,14,24-37,41-45 and 47-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-13,15,17-20,22,38-40 and 46* is/are rejected.

7)☒ Claim(s) *16,21 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicants amendment filed March 27, 2007 has been received and entered. Claim 6 has been canceled and new claim 49 has been added. Consequently, claims 1-5 and 7-49 are pending in the instant application, of which claims 7, 14, 24-37, 41-45, and 47-48 have been withdrawn from further consideration as being drawn to a non-elected invention.

### *Election/Restrictions*

1. Newly submitted claim 49 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

As set forth in MPEP 803.04, and as set forth in the pre OG notice found at www.uspto.gov/web/offices/pac/dapp/opla/preognotice/sequence02212007.pdf; nucleotide sequences with a distinct sequence are distinct inventions. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 49, drawn to newly recited SEQ ID NO: 2 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### *Claim Rejections - 35 USC § 112*

2. The rejection of claims 1-5, 8-13, 15, 17-20, 22, 38-40 and 46 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained.

Applicants are asserting that the specification defines "Yscf" as originating from any of Y. pestis, Y. pseudotuberculosis, and Y. entercolitica unless otherwise specified. Applicants further assert that the YscF proteins of Y. pestis and Y. enterocolitica include substantially similar sequences as indicated in the alignment of Fig. 1.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, these limitations define a product (YscF protein) merely by where it comes from (Y. pestis, etc), however where a product comes from is not afforded any patentable weight when the same product can be found from different sources or methods of production. [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Furthermore, Applicants specification provides a definition of "YscF." Page 9, paragraph 34, sets forth that it "includes amino acid residues in addition to or different than wild-type YscF." The upper threshold of different amino acids is not set forth, for that matter, the sequence of the wild type is not even set forth in the claims.

Accordingly, the written description element is not satisfied in view of the limitless number of molecules encompassed by the claims.

Finally, Applicants assert that the YscF proteins of Y. pestis and Y. enterocolitica include substantially similar sequences as indicated in the alignment of Fig. 1. However, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Accordingly, the claims are not limited to substantially similar sequences as shown in Fig 1, even if one of skill in the art could somehow determine what "substantially similar" to Figure 1 meant.

Claims 1-5, 8-13, 15, 17-20, 22, 38-40 and 46 are directed to "a means for providing protection to an animal against a pathogen of Yersinia" and wherein the means for providing protection is a YscF protein, as well as "protective epitopes."

Applicants specification (Page 9, paragraph 34) defines "YscF" as a protein that includes amino acid residues in addition to or ***different*** than wild-type YscF.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "means for providing protection against Yersinia or a YscF protein or protective epitopes" alone are insufficient to describe the

genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court

states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claims 1-6, 8-13, 15-21, and 38-40 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide enablement for compositions capable of providing protection against a pathogen of Yersinia is withdrawn in view of Applicants arguments.

4. The rejection of claim 40 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "having homology to SEQ ID NO: 1" is withdrawn in view of Applicants amendment.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 1-3, 5, 8-11, 13, 15, 17-18, 20, 22, 38-40 and 46 under 35 U.S.C. 102(b) as being anticipated by Titball et al is maintained.

Applicants are asserting that Titball lacks any disclosure of a YscF protein.

Applicants arguments have been fully considered but are not found to be persuasive.

Titball discloses of subunit vaccines against the F1 capsular antigen and the V antigen of Y. pestis. Applicants specification defines "YscF" as originating from any of Y. pestis, Y. pseudotuberculosis and Y. entercolitica. Clearly, this limitation has been met, since the proteins used by Titball are from Y. pestis. The question becomes is how does the "YscF" protein of the instant invention then exclude the F1 antigen and V antigen from the breadth of the claims? Given that Applicants specification defines "YscF" as including different amino acid residues than wild type YscF (Page 9, paragraph 34) the disclosure of the F1 antigen and V antigen meets every structural limitation required by the claims. (i.e., contains different amino acids than the wild type YscF protein).

The claims are directed to an immunogenic composition comprising a means for providing protection to an animal against a pathogen of Yersinia origin; and a

pharmaceutically suitable excipient, and wherein the means for providing protection is a YscF protein.

Titball et al (US Patent Number 5,985,285) disclose of immunogenic compositions comprising Yersinia pestis V antigen and Yersinia pestis F1 antigen. (See claims).

Applicants are again reminded that the specification (Page 9, paragraph 34) defines "YscF" as a protein that includes amino acid residues in addition to or ***different*** than wild-type YscF. (Emphasis added).

Accordingly, since the claims do not recite a required structure for the YscF protein, and furthermore, the specification expressly allows for unlimited sequence differences with the wild type YscF protein, the disclosure of Titball et al is deemed to anticipate the instantly filed claims.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

6. Claims 1, 8, and 22, are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart Jr., et al.

Applicants arguments are identical to those set forth above in rejection number 5, and have been fully addressed in rejection number 5.

The claims are directed to a His-tagged YscF protein.

Stewart Jr., et al (US Patent Number 6,261,561) disclose of plasmid pHis-Inv1, encoding a His-tagged Yersinia Pseudotuberculosis Invasin. (See Column 11).

Applicants are again reminded that the specification (Page 9, paragraph 34) defines "YscF" as a protein that includes amino acid residues in addition to or ***different*** than wild-type YscF. (Emphasis added).

Accordingly, since the claims do not recite a required structure for the YscF protein, and furthermore, the specification expressly allows for unlimited sequence differences with the wild type YscF protein, the disclosure of Stewart Jr., et al is deemed to anticipate the instantly filed claims.

For reasons of record, this rejection is maintained.

The following new grounds of rejection are applied to the amended claims:

***Claim Rejections - 35 USC § 112***

7. Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 40 recites the limitation "80% homology." Applicants point to paragraphs 4, 35-37 as well as Fig. 1 for support. However, not one of these sections of the

specification ever recite the term "80%." Accordingly, Applicants are required to demonstrate clear support (page and line number of the spec) for the term 80% or cancel the newly added material.

Claims 16, 21, and 23 are objected to for depending upon a rejected base claim, however claims 16, 21 and 23 are free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Navarro
Primary Examiner
April 10, 2007